Remarks

Claims 1 and 3-16 are currently pending. Claims 8-12, 15, and 16 have been canceled without prejudice. Claims 1 and 3 have been amended. Support for the claim amendments can be found in the specification and claims as originally filed. Therefore, no new matter has been added. The Applicants expressly reserve the right to prosecute further the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 USC § 120 and § 121.

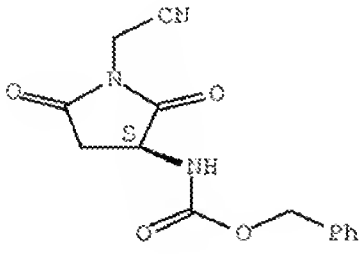
Claim Rejections Based on 35 U.S.C. § 102

Thomas

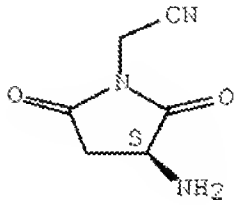
Claims 1 and 4-7 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Thomas *et al.*, WO 2004/022536 ("Thomas"). The Applicants respectfully traverse.

To anticipate a claim under §102, a reference must teach each and every element of the claim, either expressly or inherently. M.P.E.P. § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union oil Co. of California,* 8144. F. 2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as contained in the ... claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Applicants submit that the cited art does not meet this standard.

The Examiner contends that Thomas discloses two compounds (A and B depicted below) that anticipate the pending claims.



and



A B

In the parlance of the structural limitations of the rejected claims, the structures of the compounds disclosed by Thomas are set forth below.

Compound A: n is 0; L on ring A is absent; R^7 is oxo on ring A; R^2, R^3, R^4 and R^5 are H; R^6 is -CN; Y is -C(O)-; X is O; L is $-CH_2-$; and R^1 is phenyl.

Compound B: n is 0; L on ring A is absent; R^7 is oxo on ring A; R^2, R^3, R^4 and R^5 are H; R^6 is -CN; Y, X, and L are absent; and R^1 is H.

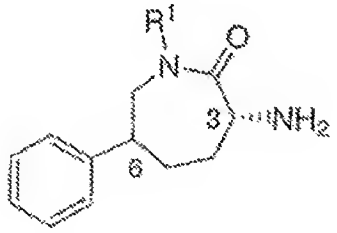
The Applicants have amended the claims to remove "oxo" from the Markush group defining R^7. Consequently, the Applicants respectfully assert that the amended claims do not read on any of the compounds disclosed in Thomas.

Burgey

Claims 1 and 4-6 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Burgey *et al.*, WO 2004/092168 ("Burgey"). The Applicants respectfully traverse.

The criteria for determining whether a reference anticipates a claim are outlined above.

The Examiner contends that Burgey discloses a compound (depicted below) that anticipates the pending claims.



, wherein R^1 is CH_2CN

In the parlance of the structural limitations of the rejected claims, the structure of the compound disclosed by Burgey is set forth below.

n is 2; L on ring A is absent; R^7 is phenyl (aryl) on ring A; R^2, R^3, R^4 and R^5 are H; R^6 is -CN; Y, X, and L are absent; and R^1 is H.

The Applicants have amended the claims to remove "aryl" from the Markush group defining R^7. Consequently, the Applicants respectfully assert that the amended claims do not read on any of the compounds disclosed in Burgey.

Accordingly, the Applicants respectfully request the withdrawal of the claim rejections based on 35 U.S.C. § 102(e).

Claim Rejections based on 35 U.S.C. § 103(a)

Claims 13 and 14 stand rejected under 35 U.S.C. § 103(a) being unpatentable over Thomas as applied to claims 1 and 4-7 above, in view of Remington's: the Science and Practice of Pharmacy, 19th edition, vol. 1, p. 806. The Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness, a number of criteria must be met. For example, all of the limitations of a rejected claim must be taught or suggested in the prior art reference (or references when combined) relied upon by the Examiner; or they must be among the variations that would have been "obvious to try" to one of ordinary skill in the relevant art in light of the cited reference(s). Moreover, one of ordinary skill in the relevant art must have a reasonable expectation of success in light of the cited reference or combination of references. Importantly, the reasonable expectation of success must be found in the prior art, and may not be based on the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); *see* MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

The Applicants believe that the Examiner has failed to state a *prima facie* case of obviousness for the rejected claims, as the cited reference does not teach or render "obvious to try" each and every element of the amended claims.

The Examiner contends Thomas discloses compounds which fall within the scope of the rejected claims. However, the amended claims do not read on the compounds disclosed in Thomas. In the parlance of the structural limitations (i.e., formula I) of the rejected claims, the compounds disclosed by Thomas contain an oxo group on ring A in the position corresponding to R^7. In contrast, the definition of R^7 in the amended claims does not encompass an oxo group on ring A.

Furthermore, based on the cited combination of references one of skill in the art would not have had a reasonable expectation of success in developing the claimed packaged pharmaceutical comprising a compound amended claim 1. The Thomas compounds differ chemically from the claimed compounds. Further, the Thomas compounds are phosphodiesterase type 4 inhibitors shown to be useful in the treatment of inflammatory and allergic disorders. In contrast, Applicants' claimed compounds are selective inhibitors of post-proline cleavage enzymes and are used to regulate glucose metabolism. Thus, due to the differences between the structure and function of the compounds disclosed in Thomas and those of the claimed compounds, one of skill in the art would not have had a reasonable expectation of success in developing the claimed packaged pharmaceutical based on the cited references.

Accordingly, the Applicants respectfully request the withdrawal of the claim rejections based on 35 U.S.C. § 103(a).

Claim Rejections – 35 U.S.C. § 112¶2

Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. The Examiner contends that claim 3, which depends from claim 1, lacks sufficient antecedent basis.

Solely to expedite prosecution, the Applicants have amended claim 3 to define R^6 as boronic acid.

Accordingly, the Applicants respectfully request the withdrawal of the rejection based on 35 U.S.C. § 112¶2.

Fees

The Applicants believe that they have provided for all required fees in connection with the filing of this Response. Nevertheless, the Commissioner is hereby authorized to charge any additional required fees to our Deposit Account, **No. 06-1448** reference **TUV-048.01**.

Conclusion

In view of the above amendments and remarks, it is believed that the pending claims are in condition for allowance. If a telephone conversation with the Applicants' Agent would expedite prosecution of the above-identified application, the Examiner is urged to contact the undersigned at (617) 832-1000.

Respectfully submitted,
Patent Group

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Date: March 28, 2011

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